European Journal of Vascular and Endovascular Surgery 44 (2012) 11–17

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

Variation in Clinical Practice in Carotid Surgery in Nine Countries 2005–2010. Lessons from VASCUNET and Recommendations for the Future of National Clinical Audit CME

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WHAT THIS PAPER ADDS

- This is the second Vascunet report on carotid surgery including previously unpublished comparison of vascular surgical practice in nine countries in Europe and Australia. The comparison includes estimations of effectiveness of current practice and utility of carotid endarterectomy (CEA). Vascunet data give a possibility to identify differences in inclusion criteria and thus give a reflection of real-life vascular service in these countries. Time trends in proportions of carotid artery stenting (CAS) versus CEA may also be identified.

ARTICLE INFO

Article history:
Received 1 July 2011
Accepted 16 April 2012
Available online 24 May 2012

Keywords:
Vascunet
CEA
Carotid surgery
Registry
Vascular surgery

ABSTRACT

Objectives: The aim of the study was to analyse variation in carotid surgical practice, results and effectiveness in nine countries.
Patients and Methods: A total of 48,185 carotid endarterectomies (CEAs) and 4602 carotid artery stenting (CAS) procedures were included in the comparison. A theoretical effectiveness of CEA provision for each country was estimated.
Results: 92.6% of the CEAs were performed according to the inclusion criteria based on the current European recommendations and had a theoretical benefit for the patient. The indication for surgery was symptomatic stenosis in 60.1% and this proportion varied between 31.4% in Italy and 100% in Denmark. The overall combined stroke and death rate in symptomatic patients was 2.3%. This varied between rates of 0.9% in Italy and 3.8% in Norway. The overall combined stroke and death rate in asymptomatic patients was 0.9%. It was lowest in Italy at 0.5%, and highest in Sweden at 2.7%. We estimated that the stroke prevention rate per 1000 CEAs varied from 72.9 in Italy to 130.8 in Denmark.
Conclusions: There is significant variation in clinical practice across the participating countries. The theoretical stroke prevention potential of CEA seems to vary between participating countries due to differences in the inclusion criteria.

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doi:10.1016/j.ejvs.2012.04.013

Introduction

VASCUNET is a joint venture of vascular registries from Europe and Australasia, administered and funded by the European Society for Vascular and Endovascular Surgery (ESVS). Since the first VASCUNET meeting in 1997 the registry has been developing and two general database reports have been published.[1,2] As part of the third report an analysis of abdominal aortic aneurysm treatment and CEA outcome data from 2003 to 2007 have been published.[3,4]

The aim of carotid endarterectomy (CEA) is to prevent strokes. During the last two decades, large randomised trials have clarified the indications for carotid intervention. The ESVS guidelines on carotid surgery were published in 2009.[5] According to the recommendations CEA for symptomatic carotid stenosis exceeding 50% is indicated if the complication rates remain low. The evidence base suggests that greatest benefit is seen if the operation is performed soon after the onset of symptoms. National guidance has been developed in most countries, such as the National Institute for Clinical Excellence (NICE) in the UK that recommends intervention within 2 weeks of the first symptom and the Department of Health has set a target of reaching a 48-h delay before 2017 (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081062).

The indications for surgery for asymptomatic stenosis are less clear, because the risk of stroke for patients with asymptomatic carotid stenosis is low. At present, the guidelines state that surgery is indicated in younger patients (<75 years) and males seem to benefit more from CEA. Another controversial issue is the role of carotid artery stenting (CAS). However, recent larger trials, ICSS[6] and CREST,[7] showed that the risk of stroke is significantly higher after stenting than after CEA, especially for symptomatic patients.[8,9] In a recent pooled analysis of 3433 randomised patients CEA was safer in the short term than stenting, because of an increased risk of stroke associated with stenting in patients over the age of 70 years, but no difference was apparent in younger patients.[10]

High-quality CEA provision cannot be reached without quality-control methods. The guidelines are based on randomised controlled trials (RCTs) whenever possible. However, actual practice is seldom a clean reflection of RCT recommendations. It is important to know how well the actual practice compares with trial recommendations. Registries reflect actual clinical practice, although low rates of case ascertainment may introduce reporting bias. Registries can also demonstrate adherence (or not) to clinical evidence. Finally, they permit analysis of geographic variation in clinical practice. This may reflect socio-economic differences or differing cultural interpretation of the evidence base. National administrative data sets may provide some information, but may lack critical clinical data about the pathway of care. Clinical and scientific registries address more specific questions for quality control and research. A significant concern with registered data is reliability. Comparison of case ascertainment against national statistics and validation of data quality is the ideal but seldom achieved in clinical practice. The problem is compounded when trying to compare national data sets due to differing cultures, and national legislation around patient privacy. Despite these flaws, registries aid harmonisation and standardisation of national data sets and can indicate where outlying behaviour may affect patient safety (see www.aaaqip.com).[11,12]

This study analyses data on CEA in eight European countries and Australia between 2005 and 2010. We look particularly at variation between countries, with emphasis on the effectiveness of CEA provision. Our final aim is to examine how well European guidelines are implemented in practice and to identify factors that affect their implementation.

Material and Methods

Case ascertainment

Data on CEAs and CASs from nine national or regional vascular registries were collected and amalgamated using common data sets accepted by all participants. Data were collected from 2005 to 2009. Australia, Denmark, Finland, Norway, Sweden and the United Kingdom included data from all 5 years. In addition, the UK included data from year 2010. Norway and Switzerland reported data for 2005–2008, Italy for 2007–2009 and Hungary from 2008 to 2009. The data from Finland and Australia are from regional and the others are from national registries. The variables and distribution of data included in the data set are presented in Tables 1 and 2 and patient demographics in Table 3.

Stratification of patients for analysis

Data were available for 53,077 carotid artery procedures; these were analysed overall and by country. Due to the differences in the registries, not all data were available from all countries. The main focus was to evaluate the differences between the nine countries in patient demographics, co-morbidities, indications, operative data, outcome and effectiveness. Due to the small proportion of CAS, these were not included in the general analysis on outcome and effectiveness reported below, but CAS patients were included in the univariate analysis and the binary logistic regression model. Data on CEAs were divided into asymptomatic and symptomatic patients in the outcome analysis. To evaluate the effectiveness of carotid surgery, CEA procedures were again divided into three categories reflecting the data derived from large RCTs[13,14] and explained in more detail in discussion. These are:

1. *Highly effective*, which included all symptomatic men with carotid artery stenosis ≥50% and symptomatic women ≥75 years of age with a stenosis ≥50%.
2. *Moderately effective*, which included symptomatic and asymptomatic <75-year-old women with ≥50% stenosis and asymptomatic men with a stenosis ≥50%.
3. *Not effective*, which included all patients with a stenosis <50% and ≥75-year-old asymptomatic women.

To assess the effectiveness of this division of patients, we calculated the crude number of strokes prevented per 1000 operations for each group: This gave estimates of 150, 75 and 0 for each of groups 1, 2 and 3, respectively.[13,14] These numbers were used in the subsequent calculations given below.

Statistical analysis

Continuous data are presented as mean values and standard deviation (SD); proportions are presented as percentages with 95% confidence intervals (CIs). CAS patients were included in the year-by-year report on procedure amounts (Table 2), univariate analysis and the logistic regression model (Table 6), but excluded in other analyses (Tables 3–5).

To evaluate the risk factors for combined stroke and death rate 30 days after the CEA or CAS, a univariate analysis was performed including pre- and perioperative variables with less than 30% of missing data and included in at least 8/9 national registries. Variables that reached $p < 0.2$ in the univariate analysis were included in a binary logistic regression model, and the included variables were indication, admission mode, procedure and country.

To estimate the effectiveness of interventions in each country, the proportion of patients in each of our three categories was

Table 1
Data collected included in the Vascunet database on carotid endarterectomies and stentings.

	Australia	Denmark	Finland	Hungary	Italy	Norway	Sweden	Swizerland	UK
Fields									
Country	×	×	×	×	×	×	×	×	×
Hospital ID	×	×	×	×	×	×	×	×	×
Patient age	×	×	×	×	×	×	×	×	×
Patient ID	×	×	×	×	×	×	×	×	×
Gender	×	×	×	×	×	×	×	×	×
Pre-operative data									
Admission date	×	×	×	×	×	×		×	×
Admission mode	×	×	×	×	×	×	×		×
Time event							×		×
Time of most recent event							×		×
Diabetes	×	×	×	×	×	×	×	×	×
Cardiac history	×	×	×	×	×	×	×	×	×
Current smoker	×	×	×	×	×	×	×	×	
Pulmonary history	×	×	×	×	×	×	×	×	
Hypertension history	×	×	×	×	×	×	×	×	
Indication	×	×	×	×	×	×	×	×	×
Grade stenosis (NASCET)	×	×	×	×	×		×		×
Grade contra stenosis				×			×		×
Previous ipsiiateral intervention		×	×	×		×		×	×
Preop rankin score				×			×		×
Operative data									
Procedure	×	×	×	×	×	×	×	×	×
CEA type	×	×	×	×	×	×	×		×
CEA patch	×	×	×	×	×	×	×	×	×
CEA shunt	×		×	×	×		×		×
Operation date	×	×	×	×	×	×	×	×	×
ASA grade	×	×	×	×	×		×	×	×
Anaesthetic	×	×	×	×	×			×	×
Post-operative data									
Haemorrhage	×	×	×	×	×	×	×	×	×
Nerve injury	×	×	×	×	×	×	×	×	×
TIA	×	×	×	×	×	×	×	×	×
Stroke	×	×	×	×	×	×	×	×	×
Myocardial infarction	×	×	×	×	×	×	×	×	×
30 day status		×	×	×	×	×	×	×	×
Discharge date	×	×	×	×	×	×		×	×
Date of death							×		
Cause of death		×							×
Return to theatre within 30 days			×	×	×	×			×

calculated and the number of strokes prevented/1000 operations was estimated for each country. We used the highest value obtained (131/1000 for Denmark) as a reference, with all other countries being given a proportional effectiveness value.

Statistical evaluation was made using SPSS 17.0 software (SPSS Inc.; Chicago, IL, USA). Continuous variables are reported as the mean ± standard deviation. Cox proportional hazard model was used as a multivariate analysis to find independent risk factor for poor outcome after the carotid procedure. Predictors of end point were identified on univariate screen using $p < 0.2$ as threshold for the inclusion in a Cox regression model. Pearson's chi-square test was used for univariate analysis and for comparing proportions. Values for $p < 0.05$ were considered significant.

Results

The data include 53,077 carotid procedures, 48,185 CEAs and 4602 CASs (Table 2). When comparing the results from an individual country to the mean figures it should be noted that Italy and UK present by far the largest numbers of treated patients. The

Table 2
The number of registered carotid endarterectomies (CEA) and carotid artery stentings (CAS) in the countries participating in the Vascunet registry during 2005–2010.

	2005			2006			2007			2008			2009(–2010[a])			Invalid data	All countries				
	CEA	CAS	CAS%	CEA	CAS	CAS%	CEA	CAS	CAS%	CEA	CAS	CAS%	CEA	CAS	CAS%		%	CEA	CAS	CAS%	Total
Australia	452	76	14.4	422	72	14.6	401	67	14.3	484	59	10.9	451	18	3.8	0	0	2210	292	11.7	2502
Denmark	288	0	0	334	0	0	346	0	0	402	0	0	458	1	0.2	0	0	1828	1	0.1	1829
Finland	144	0	0	136	0	0	180	15	7.7	229	8	3.4	255	9	3.4	0	0	944	32	3.3	976
Hungary	3	0	0	1	0	0	1	0	0	624	23	3.6	635	21	3.2	99	7.0	1264	44	3.7	1407
Italy	0	0	0	0	0	0	6781	1356	16.7	6064	1495	19.8	4782	871	15.4	0	0	17,627	3722	17.4	21,349
Norway	300	14	4.5	342	12	3.4	361	9	2.4	354	5	1.4	0	0	0	0	0	1357	40	2.9	1397
Sweden	922	43	4.5	1036	80	7.2	931	90	8.8	1097	86	7.3	1104	71	6.0	5	0.1	5090	370	6.8	5465
Swizerland	424	0	0	447	6	1.3	480	4	0.8	465	0	0	0	0	0	0	0	1816	10	0.5	1826
United Kingdom	235	0	0	2912	0	0	2747	17	0.6	4079	34	0.8	6076	40	0.7	186	1.1	16,049	91	0.6	16,326
Total	**2768**	**133**	**4.6**	**5630**	**170**	**2.9**	**12,228**	**1558**	**11.3**	**13,798**	**1710**	**11.0**	**12,236**	**1027**	**7.7**	290	0.5	**48,185**	**4602**	**8.7**	**53,077**

CEA = carotid endarterectomy; CAS = carotid artry stenting.
[a] Includes numbers from year 2010 in the data from Unided Kingdom (1521 CEAs and 4 CASs) and Hungary (4 CEAs).

Table 3
Indications, admission mode, age, gender, risk factors, type of operation and anaesthesia mode in carotid endarterectomy patients.

	Australia		Denmark		Finland		Hungary		Italy		Norway		Sweden		Swizerland		UK	
		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)		D.m. (%)
Indication asymptomatic (%)	33.1	0.3	0.0	1.3	15.6	1.1	46.1	9.2	68.6	0.0	20.5	0.0	22.8	0.1	40.4	0.0	16.8	1.2
Admission mode emergency (%)	24.6	0.3	3.7	0.1	7.0	0.6	10.2	6.2	2.1	0	5.5	0	9.3	35.8	N.a.		10.9	1.3
Mean age (SD)	72.4 (9.0)	0.0	67.9 (9.1)	0.0	68.4 (9.1)	0.0	65.9 (9.0)	0.0	72.2 (8.4)	0.0	68.2 (9.0)	0.0	70.7 (8.5)	0.0	70.6 (9.0)	0.0	72.7 (9.5)	0.0
>75 years (%)	44.7	0.0	25.4	0.0	26.5	0.0	18.7	0.0	43.4	0.0	26.5	0.0	33.8	0.0	38.1	0.0	45.6	0.0
Female (%)	29.4	0.0	32.3	0.0	31.4	0.0	39.0	0.0	31.8	0.0	33.1	0.0	32.0	0.0	28.8	0.0	31.1	0.0
Diabetes (%)	24.7	3.7	14.2	0.2	38.7	4.3	29.8	77.6	29.5	0.0	15.6	0.0	20.0	2.8	24.4	0.0	20.2	0.9
Cardiac history (%)	49.8	4.0	26.5	0.2	42.6	4.1	47.0	77.6	51.0	0.0	37.6	0.0	37.7	4.2	39.6	0.0	30.6	1.1
Hypertension history (%)	84.4	3.8	63.9	0.7	57.2	3.6	20.2	77.6	87.0	0.0	61.5	0.0	75.6	3.5	80.0	0.0	N.a.	
Current smoker (%)	14.8	4.7	42.3	0.9	34.6	7.4	58.1	77.6	16.3	0.0	37.9	0.0	32.8	12.4	53.4	0.0	N.a.	
Pulmonary history (%)	N.a.		9.5	0.4	32.4	5.0	13.7	77.6	17.0	0.0	8.9	0.0	9.8	7.4	8.4	0.0	N.a.	
Use of patch (%)	85.1	29.1	38.8	0.0	37.4	0.1	5.4	1.5	100.0	69.1	61.7	0.0	40.1	2.7	70.0	0.0	68.9	2.9
Local anaesthesia (%)	29.5	0.6	66.6	0.5	41.4	85.7	21.9	77.6	51.3	0.0	N.a.		N.a.		57.5	5.5	49.8	1.1
Eversion (%)	22.2	6.0	27.3	46.7	1.4	85.7	88.6	3.6	62.8	51.0	0.0	0.0	28.3	67.2	N.a.		7.3	3.2

D.m. = Data missing; N.a. = not applicable.

proportion of CAS was highest in Italy (17.4%) and lowest in Denmark (0.1%). Mean age was 71.7 (SD 9.1) years. The mean age for CEA patients was lowest in Hungary (65.9 years, SD 9.0), and highest in the UK (72.7 years, SD 9.5) ($p < 0.001$). The proportion of CEA patients older than 75 years varied from 18.7% in Hungary to 45.6% in the UK ($p < 0.001$). The proportion of women who had CEA was highest in Hungary (39.0%) and lowest in Switzerland (28.8%) ($p < 0.001$). All countries reported the indication for surgery as symptomatic or asymptomatic. The indication for surgery was symptomatic stenosis in 60.1% and this proportion varied from 100% in Denmark to 31.4% in Italy ($p < 0.001$). All countries but Switzerland included admission mode; 6.8% of patients were operated as emergency and the proportion of emergency operations varied from 2.1% in Italy to 24.6% in Australia ($p < 0.001$). The emergency admission for all countries varied between 4.6% and 8.5% during 2005–2009 and there was no systematic increase over time. The prevalence of risk factors is presented in Table 3.

The combined stroke and death rate in asymptomatic patients was 0.9% and it was lowest in Italy, 0.5% and highest in Sweden, 2.7%. The combined stroke and death rate in symptomatic patients was 2.3% and it varied between 0.9% in Italy and 3.8% in Norway (Table 4).

Five countries (Australia, Denmark, Italy, Switzerland and the UK) reported the mode of anaesthesia (general anaesthesia or local anaesthesia). In these countries, the proportion of local/regional anaesthesia was 44.7% varying from 20.2% in Australia to 66.2% in Switzerland. Patch was used in 50.5% and it varied from 5.6% in Hungary to 70.4% in Switzerland (Table 3).

In the estimation for theoretical effectiveness of CEA provision in each country the strokes prevented per 1000 operations varied from 72.9 in Italy to 130.8 in Denmark (Table 5). The proportion of patients that were operated according to European Society for Vascular Surgery guidelines for carotid surgery[5] was 92.3% and varied from 70.3% in Italy to 100.0% in Denmark (Fig. 1).

In multivariate logistic regression model the independent predictors for combined 30-day death and/or stroke rate were symptomatic stenosis (OR 1.37, 95% CI 1.14–1.63), CAS versus CEA (OR 1.78, 95% CI 1.36–2.33), admission mode emergency (2.04, 95% CI 1.68–2.49) and country (Table 6).

Discussion

Inclusion criteria

We found clear differences in the practice of carotid surgery in the participating countries. Outcome data are often presented without a critical description of the inclusion criteria. We tried to avoid this by calculating a theoretical effectiveness of the CEA provision in each country. From the community point of view, to make use of the full stroke preventing potential of CEA, the NNT

Table 4
Death and/or stroke rate in asymptomatic and symptomatic carotid endarterectomy patients.

	Australia	Finland	Hungary	Italy	Norway	Sweden	Switzerland	UK	Total
Asymptomatic all	0.9	2.0	2.1	0.5	2.5	2.7	1.6	1.8	1.0
Female	1.4	0.0	3.7	0.5	3.8	2.3	1.0	1.4	0.9
Male	0.6	2.5	1.0	0.5	2.0	2.9	1.9	1.9	1.0
>75 years	1.0	0.0	2.6	0.6	0.0	4.2	2.8	1.5	1.0
<75 years	0.3	2.4	2.0	0.4	3.2	2.5	1.0	2.0	1.0

	Australia	Denmark	Finland	Hungary	Italy	Norway	Sweden	Switzerland	UK	Total
Symptomatic	2.1	3.7	1.9	3.4	0.9	3.8	3.0	3.4	2.4	2.4
Female	2.2	4.0	3.9	3.1	0.7	2.5	3.4	5.6	2.5	2.5
Male	2.0	3.5	1.0	3.6	1.0	4.5	2.8	2.5	2.4	2.3
>75 years	2.6	5.0	0.9	3.4	0.9	2.4	3.3	3.8	2.4	2.4
<75 years	1.6	3.2	2.3	3.4	0.9	4.4	2.7	3.1	2.5	2.4
Emergency	3.1	6.0	3.0	4.1	3.8	7.0	3.5	N.a.	3.6	3.6
Elective	1.5	3.6	1.8	3.3	0.7	3.6	2.5	N.a.	2.3	2.1

Table 5
Carotid endarterectomies (CEAs) divided into effectiveness categories based on calculated theoretical numbers of strokes prevented at 5 years by performing 1000 CEAs. In the calculation of utility rates, year 2008 was chosen, because it represented most comprehensive data from all countries.

	I *n* (%)	SPrev (*n*)	II *n* (%)	SPrev (*n*)	III *n* (%)[a]	SPrev (*n*)	D.m.	Total	SPrev/1000	PEff %	% Population	Utility rate 2008	Utility 2008 *S*
Australia	1250 (56.6)	188	636 (28.8)	48	317 (14.3)	0	7 (0.3)	2210	106	81.4	23.2	10.9	7.3
Denmark	1384 (75.7)	208	420 (23.0)	32	0 (0.0)	0	24 (1.3)	1828	131	100.0	100	7.4	7.4
Finland	599 (63.5)	90	310 (32.8)	23	24 (2.5)	0	11 (1.2)	944	120	91.6	33.5	13.2	11.1
Hungary	484 (35.5)	73	617 (45.3)	46	132 (9.7)	0	129 (9.5)	1362	87	66.7	78.2	8.7	4.7
Italy	4734 (26.9)	710	7660 (43.5)	575	5233 (29.7)	0	0 (0.0)	17,627	73	55.7	100	12.5	3.9
Norway	806 (59.4)	121	486 (35.8)	36	65 (4.8)	0	0 (0.0)	1357	116	88.7	100	7.7	6.1
Sweden	3127 (61.4)	469	1687 (33.1)	127	275 (5.4)	0	1 (0.0)	5090	117	89.5	93.4	13.5	10.4
Switzerland	902 (49.7)	135	668 (36.8)	50	246 (13.5)	0	0 (0.0)	1816	102	78.1	100	6.0	3.6
United Kingdom	10,891 (67.1)	1634	3815 (23.5)	286	1339 (8.2)	0	187 (1.2)	16,232	118	90.4	100	6.6	5.5
Total	24,177 (49.9)	3627	16,299 (33.6)	1222	3608 (7.4)	0	359 (0.7)	48,466	100	76.5	83.7	9.6	6.7

I (Highly effective): ≥50% stenosis symptomatic men all, ≥50% stenosis symptomatic female ≥75 years old.
II (Moderately effective): ≥50% stenosis in asymptomatic men, ≥50% stenosis in symptomatic and asymptomatic female <75 years old.
III (Mildly or no effective): <50% stenosis, asymptomatic stenosis in female >75 years.
D.m. – Data missing.
PEff = proportional effectiveness, if Denmark is considered 100.
% Population = the proportion of available data from the whole population.
Utility rate 2008 = number of carotid interventions / 100,000 inhabitants in 2008.
Utility 2008 *S* = number of carotid interventions for symptomatic disease / 100,000 inhabitants in 2008.
[a] ESVS guidelines for carotid surgery do not recommend surgery for these patients SPrev = number of strokes prevented at 5 years. The estimations were 150, 75 and 0 at 5 years by performing 1000 CEAs for groups 1, 2 and 3 respectively.

Table 6
Risk factors for combined death and/or stroke rate within 30-days after the procedure (binary logistic regression model including all 53 077 patients).

	Denmark	1.37	1.05–1.79	0.022
	Finland	0.79	0.50–1.23	0.288
	Hungary	1.05	0.73–1.49	0.802
	Italy	0.26	0.21–0.33	0.000
	Norway	2.02	1.49–2.72	0.000
	Sweden	1.02	0.81–1.28	0.871
	Switzerland[a]	1.54	1.14–2.09	0.005
Indication	Reference			
	Asymptomatic			
	Symptomatic	1.37	1.14–1.63	0.001
Procedure	Reference			
	CEA			
	CAS	1.78	1.36–2.33	0.000
Admission mode	Reference			
	Elective			
	Emergency	2.04	1.68–2.49	0.000

[a] The model excludes variables if over 30% of data is missing, admission mode was not reported from Switzerland and all these cases are assumed to be elective. Therefore OR from Switzerland may be an overestimation.

figures should be as low as possible. From a patient perspective, however, the situation is different. The individual patient's interest is to have the least possible risk of stroke or recurrent stroke either with an operation or without it. In this perspective, surgery may be justified even in a less 'effective' setup. Thus, the differences should be interpreted with caution. In the most effective setup, some patients will have stroke, which might have been prevented by CEA and in the least effective group many patients will take the risk of unnecessary surgery.

In our calculations of theoretical effectiveness of the CEA we categorised the patients using available data into subgroups derived from the published NNT figures from the large RCTs.[13,14] We used the complication figures reported in the RCTs for all countries due to the fact that the registry-based data carry a risk of missing complications and thus reports may underestimate the complication rate. Also, this underestimation can be different in different countries. It should be recognised, however, that this method may underestimate the effectiveness of CEA in stroke prevention in those countries, regions or centres that have a lower complication rate. The numbers in Table 5 provide crude estimates. While the actual derived figures of strokes prevented by 1000 operations might vary with different calculations, we propose that the data are valid if it is accepted that group 2 has half the stroke prevention potential of group 1. We believe that group 3 represents clearly unnecessary operations, without demonstrable patient benefit; for example, the inclusion of younger asymptomatic women in group 2 might be discussed, but, on the other hand, there is limited evidence on the matter that no asymptomatic women should be operated.[5] The ESVS guidelines state that women have less benefit from CEA. A significant drawback of these calculations is the lack of data on delay from symptom to surgery, which is along with age the most important variable in the effectiveness. We were also not able to separate high grade from moderate stenosis using the data provided. However, the imaging modalities have changed over time and the asymptomatic trials did not show a difference between the significant stenosis groups and thus a reported 50% stenosis may be justified as a turnover point.

According to the ESVS guidelines, patients are considered symptomatic if they have suffered a carotid distribution TIA (including ocular TIA) or non-disabling stroke in the preceding 6 months. All participating countries adhere to these definitions. Some countries have validated their data in this respect, others have not, but we did not have the exact figures to analyse potential differences in the symptoms.

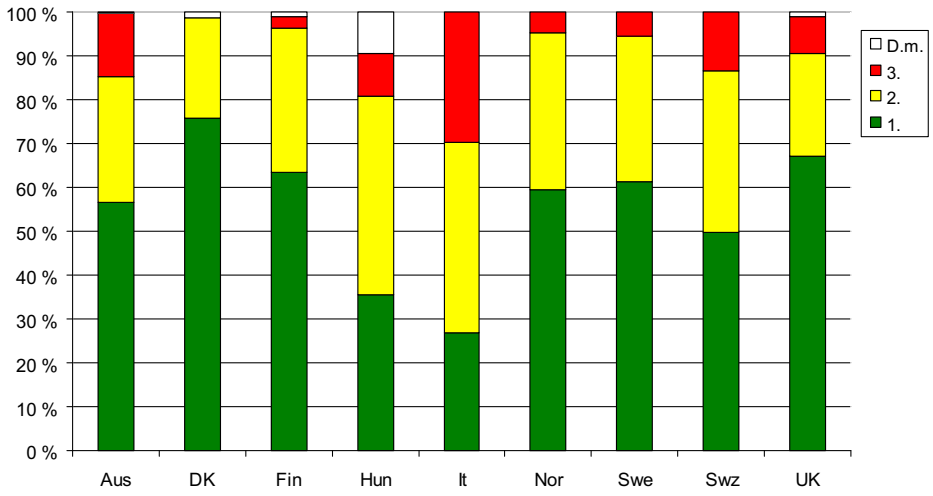

Figure 1. The proportional effectiveness of carotid provision divided into three levels for each country. 1. (Highly effective): ≥50% stenosis symptomatic men, ≥50% stenosis symptomatic female ≥75 years old. 2. (Moderately effective): ≥50% stenosis in asymptomatic men, ≥50% stenosis in symptomatic female <75 years old, <75 asymptomatic female with ≥50% stenosis. 3. (Not effective): <50% stenosis, asymptomatic stenosis in female ≥75 years. D.m. = data missing.

Of the 53,077 patients 40.2% were operated in Italy and 68.6% of them were asymptomatic. Italy and the UK represent together 37 675 CEA (i.e., 71% of all CEA). Mean, total and multivariate analysis data outputs are mainly affected by data from these two countries and therefore the data are presented separately for each country when applicable.

Asymptomatic patients over 75 and patients with a stenosis less than 50% were classified as unnecessary operations. In Denmark, no asymptomatic patients were reported. Thus, although 100% of the operations performed in Denmark were performed as suggested in the ESVS guidelines, it may not be said that the Danish indications would be in 100% accordance with the ESVS guidelines.[5] Indications for intervention seem to be the strictest in Denmark, while most countries seem to have somewhat softer inclusion criteria. Despite the ESVS guidelines there is a lack of consensus about the indications for intervention in this audit.

A recent Medicare report of 538 958 carotid procedures reported that CAS was performed in 10.5% which compares with our 0.1–17.4% and reflects the fact that CAS has not replaced CEA as the method of choice.[15]

Registry-based data are always incomplete and the complication rates might be different if controlled more meticulously.[16] As could be expected, complication rates are lower in Italy where more asymptomatic patients are operated on.

Validation

All registry-based studies have limitations and our report demonstrates these. While data were submitted for analysis to a central registry using agreed data sets, we were not able to control data validation for each country. Comparison to national statistics is only routinely carried out in a few countries (Sweden, Denmark and Finland), so completeness of data can only be estimated from comparison to national statistics, where available. External independent data validation is undertaken by Swedvasc,[12] Denmark (www.karbase.dk) and locally in Helsinki.[11] UK data are compared to national HES statistics, but not all cases are entered into the UK data. We know that incomplete data are likely to contain bias towards under-reporting poor outcomes. We recommend that national audits should incorporate some form of validation to allow external observers to form valid opinions about the accuracy of the data presented. European standards for data reporting would improve our ability to make treatment and outcome comparisons between countries.

In addition to incomplete reporting, there were significant numbers of variables missing from parts of the data set. We chose to exclude the variables where over 30% of the data were missing. Improving both the number of cases submitted and the completeness of the data set are key steps to improving the value of registry data.

Utility of CEA

Table 5 presents differences in the national utility rates for CEA in 2008. These reflect the proportion of asymptomatic patients, and adherence to the RCT evidence base for intervention. The utility rate of a representative year 2008 gave 6.0–13.5 operations per 100,000 inhabitants in the included area, lowest in Switzerland and highest in Sweden. If only symptomatic patients would have been operated, the corresponding utility rate varied between 3.6 in Switzerland and 11.1 in Finland. Patel et al. presented a utility rate of 300/100,000 Medicare beneficiaries (for people over 65 years). They highlighted a nearly ninefold difference between the highest and lowest rates of CEA across the US.[17] The proportion of people over 65 years of age is around 12% in the US and not all are included in Medicare; thus, the figures seem higher than the ones in Vascunet countries. Taha et al. estimated that if all the patients in the most effective group were operated upon (≥70% stenosis with TIA or minor stroke), then the estimated need for CEAs would be 17.1 per 100,000 Finnish inhabitants.[18]

This article demonstrates that registry data can reveal national differences in intervention rates with differing utility and effectivity. Validation and critical analysis of registry data are in the interests of patients, clinicians and politicians.

Conclusions

Carotid surgery seems to be safe in all of the reporting countries and the outcome data compare well with the results from RCTs and published register outcome data. There is no evidence that CAS has been replacing CEA during recent years. There are major differences in the theoretical stroke prevention potential of the CEA practice in the participating countries. We recommend

that the participating countries need to agree on standards for national clinical audit.

Acknowledgements

Vascunet Steering Committee is grateful to the Council of the ESVS for supporting and financing this project, and for all the colleagues in the participating centres contributing to the different national databases. Without the daily input from all the participating surgeons registering their operations, this work would not have been possible.

Conflicts of Interest

None for any of the authors.

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